HDC Neuro-Trace® II

Portable Nerve Stimulator for Nerve Location

Instructions For Use

HDC®
Corporation

INSTRUCTIONS FOR USE (Neuro-Trace® II)

1. Product Description

The Neuro-Trace® II is a portable battery powered nerve stimulator designed to be used for regional anesthesia to perform peripheral nerve blocks. The Neuro-Trace II can be used for all plexus blocks of the upper and lower extremity. The instrument is designed to effect a motor response from nerves to determine their location. The Neuro-Trace II can be an aide to the clinician during difficult or complicated nerve blocks, but it is only an aide, and its use is no substitute for knowledge of basic anatomy or regional block techniques. The Neuro-Trace II is designed to be used in conjunction with insulated needles for regional anesthesia procedures.

Special Note: This unit is for use by trained Anesthesiologists and Anesthesia Technicians only.

2. Indications

The Neuro-Trace® II is indicated for the following:

- Peripheral Nerve Blocks (Plexus) of the upper and lower extremity.

3. Contraindications

- Cardiac Pacemakers
- Cardiac electrical imbalances
- Simultaneous connection to a high-frequency surgical device
- Presence of explosive substances

4. Warnings

- Electrical stimulation to the carotid sinus area may alter cardiac rate or rhythm
- Electrical stimulation in the area of the larynx may cause muscle spasm and compromise the airway.
- Cardiac patients with pacemakers should be observed with appropriate monitors before and during electrical stimulation. Interference with the pacemaker may alter rhythms and cardiac output.

5. Potential complications

- Vessel puncture
- Nerve injury
- Bleeding
- Infection
- Paraesthesia

6. **Design Features**
The HDC Neuro-Trace II is a battery operated pocket-sized device. The unit has a built-in operational test circuit to allow the user to pre-test for proper function and preset operational parameters.

A special feature of the Neuro-Trace II is its ability to adjust to the patient's internal resistance. This feature assures that there is enough of the displayed current available to elicit a motor response from higher resistance patients.

On/Off
The Neuro-Trace II is designed to activate when the leads are connected to the patient or grounded.

Current Regulator
To adjust current from 0.1mA to 5.0mA, turn the SETPOINT knob clockwise and read the adjusted current output on the LED screen.

Digital Display
The digital display has a dual function. The default display indicates the selected current beginning at 0.1mA and to the maximum setting of 5.0mA. The screen will also display the selected pulse rate when the RATE button is depressed and held momentarily.

Output LED Indicators
The green LED signals that the unit is on and producing the current setting displayed on the screen. The rate at which it flashes corresponds to the selected pulse rate, e.g., one flash per second corresponds to one pulse per second etc.

The second color for the LED is orange and this color appears as an indicator that the display current setting is not being delivered to the patient either because of the patient's excessive internal body resistance or due to a poor or loose connection component.

Frequency Adjustment
The pulse rate is adjusted by momentarily depressing the RATE (white) button. The selected pulse rate will appear on the screen as an integer, which indicates the impulse frequency (number of pulses per second). The pulse rate can be adjusted between 1 to 5 Hz.

Audio Tone
The Neuro-Trace II has a built-in audio tone (beep) that sounds with each pulse of current. This feature allows the user to monitor the pulse frequency without looking at the display screen. The tone can be silenced by momentarily depressing the TEST (black) button.

Output Jack
The main bipolar cable must be plugged into this jack before other connections are made. The cable must be fully inserted for proper functioning.

7. Operating Instructions

Test Button

To test the functionality of the unit, press and hold the TEST button in the down position while checking the following:

- Digital display shows current setting.
- Green LED blinks at default pulse setting (1 HZ= 1 blink per second).
- Audio tone (beep) sounds in synchrony with pulse signal.
- Slowly turn SETPOINT knob and observe changes in current setting.
- Momentarily depress RATE button (white) and pulse frequency changes by one Hz.
- Momentarily release the TEST button and the beep is silenced.
- While turning the SETPOINT knob from 0.1mA to 5.0mA the LED will change from green to orange if the units battery is low.
- The Neuro-Trace II is designed to turn on when connected to a patient. Shorting the leads will simulate the connection and activate the unit.

Operating Instructions

1. Verify proper function of Neuro-Trace II by activating the TEST circuit. Preset current and desired pulse rate.

2. Insert the lead cable into the output jack of the Neuro-Trace II.

3. The ground electrode portion of the lead is attached to the EKG type pad and placed on the patient in the general area of the procedure (within 40cm).

4. Attach the needle electrode to the post on the hub of the Neuro-Trace or similar designed needle.

5. The unit is now ready to use following proper protocol for performing Peripheral Nerve Blocks (Plexus) of the upper and lower extremity.

Special Note: As stated early in this document - This unit is for use by trained Anesthesiologists and Anesthesia Technicians only.

Technical Summary

Equipment Classification	Internally powered - Type BF
Power Source	9 volt battery
Output	
Current Range	0.1 to 5.0mA, adjustable constant current
Pulse Frequency	1 to 5 Hz, adjustable
Pulse Width	.5 -.6 milliseconds
Voltage	60 Vp-p maximum
Indicators / Display	
Green LED	Full current being delivered
Orange LED	Less than full current being delivered or low battery
2 Digit Display	0.1 to 5.0 mA and1 to 5 Hz
Housing material	ABS Plastic
Unit Dimensions	6.7 X 12 X 2.5 cm
Warranty	One year from time of purchase (Battery not included)

Innovations in Anesthesia

HDC Corporation
628 Gibraltar Court Milpitas, California 95035 USA
Phone: 408-942-7340 Toll Free: 800-227-8162 Fax: 408-586-8680
http:\\www.hdccorp.com

An ISO 9001 company

U.S. Federal law restricts this device to sale by or on the order of a physician.
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